JAN - 9 2001

K003072

Bülach Manufacturing and Sterilization Site 510(k) Notification

1. 510(K) SUMMARY

Name and Address of Sponsor:

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035
(888) 345-0374

Device Classification:

Class II and III (Various FDA Product Codes)

Date Prepared:

September 29, 2000

Establishment Registration Number:

1028232

Device Names:

PRODUCT	BIOTRONIK PROPRIETARY NAME	CLASSIFICATION	CLASSIFICATION NAME	FDA PRODUCT CODE
Endocardial Leads	ELC Elox Polyrox Retrox Synox TIR/TIJ YP	Class III (21 CFR 870.3680(b))	Cardiovascular Permanent Pacemaker Electrode	DTB
Adapters	A1-A A1-B A1-ABP A1-MBP A1-40-MBP PEH Sleeve	Class III (21 CFR 870.3620)	Pacemaker Lead Adapter	DTD
Pacemaker Lead Sealing Caps	BK-N BK-A BK-B BK-IS	Class III (21 CFR 870.3680)	Cardiovascular Permanent Pacemaker Electrode (Accessories)	DTB
Lead Fixation Sleeves	EFH-22 EFH-25 EFH-27	Class III (21 CFR 870.3680)	Cardiovascular Permanent Pacemaker Electrode (Accessories)	DTB
Pacing Lead Stylets	S xx-Y*	Class II (21 CFR 870.1380)	Catheter Stylet	DRB
Guide Wires	GALEO GALEO Hydro	Class II (21 CFR 870.1330)	Catheter Guide Wire	DQX

* Y = F, J, K, S, RX, or RXJ

General Description and Predicate Devices:

BIOTRONIK proposes serial production of bradycardia pacing leads, guide wires and various accessories at an additional manufacturing and sterilization facility (BIOTRONIK AG) in Bülach, Switzerland.

BIOTRONIK believes that the previously approved products cleared through 510(k) notifications and manufactured and sterilized at BIOTRONIK GmbH & Co. in Berlin, Germany are appropriate as predicate devices for the products manufactured and sterilized in the Bülach, Switzerland facility. **Table 1** provides a list of the products that may be manufactured and/or sterilized at BIOTRONIK AG in Bülach, Switzerland and the 510(k) notifications under which the products were cleared.

Indications for Use:

Pacing Leads –

BIOTRONIK's endocardial pacing leads are indicated for permanent pacing and sensing. Endocardial pacing leads with a bipolar (BP) IS-1 connector configuration are designed for use in conjunction with implantable pulse generators with IS-1 headers. The leads may be used with single or dual chamber pacing systems.

The straight lead models are intended for placement in either the right atrium or right ventricle. The JBP lead models have a pre-formed J-shaped distal end to facilitate lead placement in the right atrial appendage.

Guide Wires –

GALEO and GALEO Hydro coronary guide wires are indicated to facilitate the placement of balloon dilation catheters or other interventional devices with compatible guide wire lumen during an interventional procedure.

Manufacturer/Sterilization Site:

BIOTRONIK GmbH & Co.
Woermannkehre 1, D-12359 Berlin, Germany
011-49-30-689-05-304

Manufacturer Registration Number:

9610139

Contact Person and Phone Number:

Jon Brumbaugh
Director, Regulatory Affairs
Phone (888) 345-0374
Fax (503) 635-9936

Contract Manufacturing/Sterilization Site:

BIOTRONIK AG
Ackerstraße 6, CH-8180 Bülach, Switzerland
011-41-1-864-5169

Contract Manufacturer Registration Number:

8043892

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2001

Mr. Jon Brumbaugh
Biotronik, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Re: K003072
Pacing Leads, Guide Wires and Various Accessories
Regulatory Class: III (three)
Product Code: 74 DTB
Dated: September 29, 2000
Received: October 3, 2000

Dear Mr. Brumbaugh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003072

Device Name: List of applicable devices is provided on the following page.

Indications For Use:

PACING LEADS

BIOTRONIK's endocardial pacing leads are indicated for permanent pacing and sensing. Endocardial pacing leads with a bipolar (BP) IS-1 connector configuration are designed for use in conjunction with implantable pulse generators with IS-1 headers. The leads may be used with single or dual chamber pacing systems.

The straight lead models are intended for placement in either the right atrium or right ventricle. The JBP lead models have a pre-formed J-shaped distal end to facilitate lead placement in the right atrial appendage.

GUIDE WIRES

GALEO and GALEO Hydro coronary guide wires are indicated to facilitate the placement of balloon dilation catheters or other interventional devices with compatible guide wire lumen during an interventional procedure.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003072

(Optional Format 3-10-98)

PRESCRIPTION X -OR- OVER-THE-COUNTER ____

Device Names:

ELC 35-UP; ELC 35-UP

Elox 45-BP; Elox 53-BP; Elox 60-BP

PX 53/15-BP; PX 60/15-BP; PX 53-BP; PX 60-BP

RX 45-JBP; RX 53-JBP; RX 53-BP; RX 60-BP

SX 53/15-BP; SX 60/15-BP; SX 53-BP; SX 60-BP; SX 45-JBP; SX 53-JBP

TIR 53-BP; TIR 60-BP; TIR 53-UP; TIR 60-UP; TIJ 45-UP; TIJ 53-UP

YP 45/15 BP; YP 53/15 BP; YP 60/15 BP

A1-A; A1-B; A1-MBP; PEH Sleeve

BK-N Sealing Cap; BK-A Sealing Cap; BK-B Sealing Cap; BK-IS Sealing Cap

EFH-22; EFH-25; EFH-27

S 45-S; S 53-S; S 60-S; S-45-J; S-45-K; S-53-J; S-53-K; S-60-J; S-60-K; S-45-F; S-53-F; S-60-F; S-45-RXJ; S-53-RXJ; S-53-RX; S-60-RX

GALEO HS 014; GALEO S 014; GALEO M 014; GALEO F 014; GALEO HF 014; GALEO S-J 014; GALEO M-J 014; GALEO F-J 014; GALEO ES 014; GALEO EW 014

GALEO Hydro HS 014; GALEO Hydro S 014; GALEO Hydro M 014; GALEO Hydro F 014; GALEO Hydro HF 014; GALEO Hydro ES 014; GALEO Hydro S-J 014; GALEO Hydro M-J 014; GALEO Hydro F-J 014